



Posted: 02/16/11jl

CANNON BUILDING
861 SILVER LAKE BLVD., SUITE 203
DOVER, DELAWARE 19904-2467

STATE OF DELAWARE
DEPARTMENT OF STATE

TELEPHONE: (302) 744-4500
FAX: (302) 739-2711
WEBSITE: WWW.DPR.DE.LAWARE.GOV

DIVISION OF PROFESSIONAL REGULATION

PUBLIC MEETING NOTICE:	BOARD OF PHARMACY
DATE AND TIME:	Wednesday, January 19, 2011 at 9:30 a.m.
PLACE:	Conference Room A, Cannon Building 861 Silver Lake Blvd., Dover, DE 19904
APPROVED:	February 16, 2011

MEMBERS PRESENT

Sebastian Hamilton, R.Ph, Professional Member, President
Howard Simon, R.Ph, Professional Member, Vice President
Sandra Robinson, R.Ph, Professional Member
Geoffrey N. Christ, Esq., R.Ph, Professional Member
Joli Martini, R.Ph, Professional Member
Don Holst, R.Ph, Professional Member

MEMBERS ABSENT

Carolyn Calio, Public Member
David Bonar, Public Member

DIVISION STAFF/DEPUTY ATTORNEY GENERAL PRESENT

David W. Dryden, R.Ph., J.D., Executive Secretary
Patricia Davis Oliva, Deputy Attorney General
Judy Letterman, Administrative Specialist III

ALSO PRESENT

Theresa Forbes
Ainsley Copied
Deborah Hamilton
Cheryl Heiks
Joanne Krakowiak
Mayanne Holzapfel
Chai Godde
Todd Cikvanac
Kalpit Patel
Angelo Chiari
Ashley Mooney
Lauren Diefenderfer
Amy Fortmann
Tiffany Sorey
Ohufenu Afijaka
George Fleming
Stephen Hampton
Harold Janes

Julia LaBadia, Court Reporter

CALL TO ORDER

Mr. Hamilton called the meeting to order at 9:30 a.m.

REVIEW OF MINUTES

A motion was made by Mr. Simon, seconded by Mr. Holst, to approve the November 17, 2010 minutes as amended. The motion was carried by Mr. Hamilton, Mr. Simon, Mr. Christ, Ms. Martini and Mr. Holst. Ms. Robinson abstained.

PRESIDENT'S REPORT

Mr. Hamilton reported that he had read an article that Illinois has proposed a House Bill which would allow pharmacies to “take back” medication from the public. He had contacted the State Board office to discuss the proposed legislation and is waiting for a response. A copy of the article will be forwarded to the members.

Mr. Hamilton stated that there was some confusion with Delaware's required prescription security features and whether other state prescriptions had to follow these standards. Mr. Dryden stated that the Delaware requirements were only for prescriptions written in Delaware by Delaware licensed practitioners.

UNFINISHED BUSINESS

Legitimate Medical Purpose – Internet Pharmacy Proposal

No report

Drug Disposal and Distribution Review

Mr. Dryden reported that he had been contacted by DEA and that a national drug disposal event had been scheduled on April 30, 2011 from 10 am to 2 p.m. One of the changes from the previous national DEA event was that patients will be allowed to dispose of liquid medication. The disposal sites for all three counties have not yet been determined.

Regulation 7 Review

Mr. Dryden informed the Board that the Committee met on January 11, 2011. The Committee found that the current regulations should be amended to further safety and welfare standards for veterinary medications. The Committee was concerned about the inappropriate human use of medications that were legend for human consumption but were non-legend medications in the area of veterinary medicine. Committee members disagreed whether the Board's power and authority should be increased to cover non-legend veterinary medication. An increase in authority could require prescriptions for non-legend veterinary medications beyond the parameters set by the FDA.

The Board did not make a decision whether they should propose the above statutory authority. They requested another Committee meeting for further information on the issue.

State of Emergency Issue Update

Mr. Holst presented the Board with Department of Safety and Homeland Security's proposed regulations governing travel restrictions during a State of Emergency. The proposal addresses first responders, essential personnel, and the three levels of driving bans. Under the proposed regulation pharmacists could travel during a level 1 and 2 driving ban. Any pharmacist driving while under a Level 2 ban must carry appropriate identification of their professional license. Pharmacists would be banned from driving under a Level 3 driving ban.

A motion was made by Ms. Robinson, seconded by Mr. Simon to amend the agenda and review items 5.1 Pharmacist-in-Charge Interviews and 5.2 Pharmacist Consultant Interview. The motion was unanimously carried.

A motion was made by Mr. Holst, seconded by Mr. Christ to back to agenda item 4.5. The motion was unanimously carried.

Regulation 5 Disposal Issue Review

Ms. Robinson informed the Board that she and Ms. Davis-Oliva had discussed changes to the proposed draft of House Bill 235. This bill was introduced during the last legislative session, but did not pass the session due to concerns about the Department of Safety and Homeland Security's added amendment. Ms. Robinson stated she had been contacted by Representative Carson who has an interest in this bill and would like to have the final draft by March so that it can be introduced before the end of this year's session.

Mr. Dryden and Ms. Davis-Oliva will work on a draft that will be agreeable to both the Board and the Department of Safety and Homeland Security.

Out of Country Distributors Review.

Mr. Dryden informed the Board that part of the requirements for a distributor application is a criminal background check (CBC) of the company's designative representative (DR) and their supervisor. The Board currently has an application from a facility which is from a country outside of the United States. After discussion, a motion was made by Mr. Christ, seconded by Ms. Robinson to require a CBC from the country of origin and if they do not have this requirement to waive the CBC for their application. The motion was carried by Ms. Robinson, Mr. Christ, Ms. Martini and Mr. Simon. Mr. Holst was opposed and Mr. Hamilton abstained.

Disciplinary hearing-Complaint 13-08-09- Harold Janes

Mr. Hamilton called the hearing to order at 10:15 a.m.

A motion was made by Mr. Holst, seconded by Mr. Simon to go off the record and into deliberations. The motion was carried.

A motion was made by Ms. Robinson, seconded by Ms. Martini to go back on the record. The motion was unanimously carried.

A motion was made by Mr. Holst, seconded by Ms. Martini that the State did not provide burden of proof of a violation of 24 Del C. § 2515 (a)(2), the State did provide proof of a violation to 24 Del C. § 2525 (a)(6) however this did not warrant a discipline.

The motion was unanimously carried.

Verbatim testimony was taken by the court reporter

Website Update

A request to update the Board member list on the website has been sent to IT.

Signing of Consent Order – Francis J. D’Allura, R.Ph

The Board previously reviewed and agreed to the Consent Order at the April 2010 meeting.

The Consent Order was signed by the members present.

Regulation 8 – Pedigree

Mr. Dryden received a request from Representative E. Bradford Bennett concerning Regulation 8 and the pedigree issue. Mr. Dryden had drafted a response which was reviewed by the Board.

A motion was made by Mr. Christ, seconded by Mr. Simon to send the letter as written to Representative Bennett. The motion was unanimously carried.

Regulation 5.1.13.16

The Board will need to make a change to this rule by eliminating the word “only” and “via a facsimile”. Ms. Davis-Oliva will make the change and send it to the Register of Regulations to be published in the March registry. The rule hearing will be scheduled for the Board’s April meeting.

A motion was made by Mr. Holst, seconded by Mr. Christ to amend the agenda and review item 5.7 Non-Resident Facility Complaint Review. The motion was unanimously carried.

NEW BUSINESS

Pharmacist-In-Charge (PIC) and Consultant Interviews

Mr. Simon conducted the PIC interviews for Oluwafemi Afilaka, Kalpit Patel, Ashley Mooney, Amy Fortmann and Ainsley Gopie.

Mr. Simon conducted the consultant interviews for Terry Forbes and George Fleming.

Pharmacist Licensure Ratifications

A motion was made by Mr. Simon, seconded by Ms. Robinson, to ratify the applications of Tawakalit Ologunbe, Betsy Campana, Megan Moncrief and Milton Gordon. The motion unanimously carried.

Pharmacist Application Reviews

The Board reviewed and discussed the application of Vitthal Patel, who had a previous discipline in another state arising out of a criminal conviction. The Board determined it was not on the list of crimes that could prevent licensure.

A motion was made by Mr. Holst, seconded by Mr. Simon, to approve his application for licensure. The motion unanimously carried.

Pharmacy Application Review(s)

Mr. Dryden explained that the Board office had received a distributor application for Superior Medical Supply, Inc. whose controlled substance registration had been suspended by the DEA but who had since been registered. The Board reviewed the file.

A motion was made by Mr. Christ, seconded by Ms. Robinson to license the candidate. The motion was unanimously carried.

Schedule Disciplinary Hearings

The Board had concerns with hearings and other disciplinary proceedings coming from minor complaints of medication errors. The Board President and Executive Secretary will review all pending complaints before scheduling a hearing is scheduled.

Non-Resident Facility Complaint Review

Mr. Dryden informed the Board that during the renewal period, non-resident facilities inform the Board of other state disciplines. Actions in the other states routinely do not have any affect on the Delaware license but the complaint process proceeds. Complaints for these out-of-state actions are drafted and recognized. A great deal of work occurs for these licensees with virtually no action ever being taken by Delaware against the licensee since the licensee has addressed the discipline in the state of initial action. We currently have 40-50 actions from the renewal of two years ago and have another 40-50 current similar actions from the recent renewal.

Mr. Dryden asked the Board for a mechanism which would address this issue.

Committee Reports

Joint Practice Committee – Don Holst and Howard Simon – No report.

Physician's Assistant Report – Sebastian Hamilton, R.Ph: No report.

Newsletter – Sandy Robinson, R. Ph., David Dryden, R.Ph., J.D, and Joli Martini, R. Ph.: No report.

Ms. Robinson informed the Board that there is a new law concerning driving under the influence of medication. It is treated the same as a D.U.I and recommends adding it to the next newsletter.

Legislative – Sandy Robinson, R.Ph, Howard Simon, R.Ph, Sebastian Hamilton, R.Ph, Don Holst, R.Ph, Geoffrey Christ, R.Ph., Esq., and David Dryden, R.Ph., J.D.:

Ms. Robinson will continue to work on House Bill 235 so that it can be sent to Representative Carson by March 2011.

Continuing Education – Sandy Robinson, R. Ph., Geoffrey Christ, R.Ph., Esq., and Joli Martini, R. Ph.:

The audit reviews are almost complete. Licensees not in compliance will be notified.

Consumer Affairs – Carolyn Calio, and David Bonar: No report.

Professional Liaison – Sandra Robinson, R.Ph. and Joli Martini, R.Ph:

Ms. Robinson informed the Board that:

- The DSHP Holiday Gathering will be on January 29 at the Iron Hill Brewery in Newark and 1 CE will be offered.
- She attended the DPS meeting presentation, Heart Truth & Death: Heart Healthy Women on January 18, 2011
- The tentative Convention schedule is May 25, 26, & 27 at the Atlantic Sands in Rehoboth. Submit names for awards.
- Two scholarships will be awarded at the convention.
- Retreat in Dewey Beach for practitioners with 10 years or less, date to be announced.
- Smyrna Police are interested in being a location for the DEA “take back” program.

MPJE Study Committee – Don Holst, R.Ph, Sebastian Hamilton, R.Ph, and David Dryden:
No report.

Controlled Substance Liaisons – Geoffrey Christ, Howard Simon, and Dave Dryden: Mr.

Simon reported that the controlled substance committee meeting was re-scheduled and will meet on February 2, 2011 at Buena Vista.

Substantially Related Crimes Committee - Geoffrey Christ, Howard Simon, Patricia Davis Oliva, and Dave Dryden: Mr. Christ stated he will work with Ms. Davis-Oliva to work on updated the Board’s crimes list.

Board Correspondence

There was no correspondence.

Inspection Report

Ms. Kluger reported that since the November Board of Pharmacy meeting the following inspections and activities were completed:

- 1 - Opening pharmacy inspection
- 2 - Nursing Homes
- 2 - Pharmacy Inspections
- 1 - In-patient Hospice inspection
- 3 - Medical Aid Clinics and 1 Surgery Center
- 2 - Follow-up inspections
- 3- Pre-inspections
- 1 - Gas supplier
- 2 - Manufacturers inspections with DEA and FDA
- 2 - Research Labs inspections with DEA Agents

1 - Dog Handler

When deficiencies are found during the inspection process or audits of controlled substances are not acceptable, the office requires written responses from the pharmacist-in-charge (PIC) or notifies the facility that a re-inspection will occur. There is one outstanding request for a response at present.

During pharmacy inspections and compliance with Regulation 14 it was noted that documentation of current CPR and immunization certificates are not found on site. Notification of State Registry or the patient's physician is not consistently done.

By way of a nursing home inspection, Ms. Kluger discovered that some nursing home administrations may be putting pressure on the Pharmacy providers to dispense controlled medications to the patients, before properly signed prescriptions from the physicians have been received. This is not in compliance with federal law. This will be investigated in the next few months by concentrating on nursing home and nursing home provider inspections and correspondence.

Other Business before the Board

Mr. Hamilton informed the Board that he will ask Mr. Dryden for an update on the Renaissance Pharmacy since it appears to be closed.

Public Comments

Mr. Divincenzo, ONDD, informed the Board of a growing problem in the State of Florida and asked for guidance from the Board. Practitioners in the State of Florida are issuing prescriptions, the patient is flying to Delaware, paying cash to have the prescription filled and then flying back to Florida. He has been contacted by some pharmacists who have stated that they were not comfortable filling the large prescriptions. When these pharmacists refuse to fill the medication in their pharmacy the patient simply goes to a different pharmacy. He recommended that this information be placed in the newsletter.

Mr. Hamilton recommended that this issue be added to the Boards agenda.

Next Scheduled Meeting

The next meeting is scheduled for February 16, 2011.

Adjournment

A motion was made by Mr. Christ, seconded by Ms. Martini, to adjourn the meeting. The motion unanimously carried. The meeting was adjourned at 12:27 p.m.

Respectfully submitted,

Judy Letterman
Administrative Specialist III